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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,486	01/04/2002	Andrew M. Scharenberg	B0662/7026	4102

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,486	SCHARENBERG, ANDREW M.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12 and 34* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 6-9, 12 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 6 and 12 have been amended and claims 16, 20, 24, 25, 32 and 36 have been cancelled as requested in the amendment filed on October 26, 2004. Claims 1-9, 12 and 34 are pending in the instant application.

Claims 2-3 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on January 26, 2004.

Claims 1, 4, 6-9, 12 and 34, in so far as they are directed to an isolated nucleic acid molecule of SEQ ID NO: 29 encoding a polypeptide of SEQ ID NO: 30 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on October 26, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 1, 4, 6-9, 12 and 34, as amended, stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 3 of Paper mailed on March 29, 2004.

Applicant traverses the rejection on the premises that "the ion channel sequences of the invention are useful in identifying drugs that can be used to block lymphocyte proliferation" and, further, to regulate the amount of intracellular calcium stores (bottom at page 7 of the Response). Applicant further submits that the according to the knowledge in the art, "calcium ions in T cells are critical for T cell activation" and that "antigen-induced calcium ion influx into mast cells [causes] the release of histamine" (middle at page 8). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The importance of calcium in general and intracellular calcium in particular in cellular physiology is well known and never doubted by the Examiner. The importance of calcium channels, transmembrane polypeptides that modulate Ca^{2+} flux "into" and "out of" a cell, is also well established. However, to support a practical utility of this specific nucleic acid of SEQ ID NO: 29 and encoded protein of SEQ ID NO: 30 corresponding to SOC-3/CRAC-2 (page 9, line12), there must be a disclosure of either a specific biological role for this SOC-3/CRAC-2 or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

A specification can meet the legal requirements of utility and enablement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide, or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan. In the instant case, the specification provides a description of novel polynucleotide encoding an asserted calcium channel SOC-3/CRAC-2 and hypothesizes that this novel channel is responsible of "modulating the supply of calcium to refill intracellular stores when depleted". There appears to be no

disclosure of any specific physiological function that is directly associated with or regulated by the novel claimed SOC-3/CRAC-2. In order to practice the claimed invention, a skilled practitioner would have to perform further research to establish what is the biological role that could be regulated by "pharmacological reagents for inhibition of SOC/CRAC channel function" (bottom at page 7 of the Response). It is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. Therefore, since the instant specification does not disclose a substantial practical use for the nucleic acid and the protein encoded thereby in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 1, 4, 6-9, 12 and 34 also stand rejected under 35 U.S.C. 112, first paragraph for reasons of record in section 4 of Paper mailed on March 29, 2004. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 1, 6-9, 12 and 34 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in section 4 of Paper mailed on March 29, 2004.

Applicant submits that recitation of hybridization conditions "allow[s] one of ordinary skill in the art the means to determine structural similarity between nucleic acid molecules" (middle at page 9 of the Response). Applicant argues further that "[o]n the issue of degeneracy raised by he Examiner, the Applicant has provided amino acid sequence data which would allow one of ordinary skill in the art the information required to determine further structurally related nucleic acid molecules". These arguments have been fully considered but are not deemed to be persuasive for the reasons that follow.

The instant specification provided the description of a nucleic acid molecule of SEQ ID NO: 29, which encodes a protein, designated SOC-3/CRAC-2, which has the amino acid sequence of SEQ ID NO: 30. However, the instant claims are drawn to isolated nucleic acid molecules with deletions, additions and substitutions which code for SOC-3/CRAC-2 polypeptide, nucleic acid molecules that differ from the nucleic acid molecule of SEQ ID NO: 29 due to the degeneracy of the genetic code, various unique fragments of SEQ ID NO: 29 and polypeptides encoded by these nucleic acid molecules. Thus, the specification only describes a nucleic acid molecule having the amino acid sequence of SEQ ID NO: 29 and polypeptide of SEQ ID NO: 30, and fails to teach or describe any other nucleic acid molecule or protein which lacks these nucleic or amino acid sequence structure and has any relevance to SOC-3/CRAC-2. Therefore, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Claims 1, 4, 9, 12 and 34 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in section 6 of Paper mailed on

March 29, 2004. Applicant submits that "[t]here are several programs available and known to those skilled in the art to translate a complement nucleic acid to the coding strand for that nucleic acid and this can be performed with no more than ordinary skill" (middle at page 10 of the Response). Applicant is advised that claim 1, as originally filed, encompasses a nucleic acid molecule, which hybridizes to a nucleic acid molecule of SEQ ID NO: 29 (which makes the claimed nucleic acid complementary to SEQ ID NO: 29) and "which code for a SOC/CRAC polypeptide". While it is true that it is not difficult to produce a "coding" sequence from a complimentary sequence; however, this appears to be not what is claimed in claim 1. Applicant is advised that if it is Applicant's intention to include a step of converting a complementary sequence into coding sequence using a suitable program, then such step should be recited within claim 1 to satisfy the enablement requirement. Otherwise, Applicant might consider rewriting the claim so that a coding sequence encodes a SOC/CRAC calcium channel polypeptide.

9. Claim 1, as amended, stands vague and indefinite in so far as it employs the term "SOC/CRAC" as a limitation for reasons of record in section 10 of Paper mailed on March 29, 2004. Applicant is advised that because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "SOC/CRAC", one would not be able to determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

10. Claim 1 further stands vague and ambiguous with respect to section (b) for reasons of record in section 11 of Paper mailed don March 29, 2004. It is not clear and cannot be

determined form the claim or the instant specification how a "deletion" of a nucleic acid can hybridize to another nucleic acid.

11. Claim 12 stands indefinite and vague for recitation "unique fragment" for reasons of record in section 12 of paper mailed on March 29, 2004.

12. Claim 6 further stands rejected under 35 U.S.C. 112, second paragraph for reasons of record in sections 13 and 14 of Paper mailed on March 29, 2004. Applicant's reasoning that one of ordinary skill in the art can research the Genbank website to obtain information, which would clarify the claimed subject mater, is not persuasive.

13. Claim 34 stands vague and ambiguous for reasons of record in section 15 of Paper mailed on March 29, 2004. In response to Applicant's argument (page 12, section vii) of the Response), there appears to be no support for definitive recitations that could be found on page 18 of the instant specification, as filed, as asserted by Applicant.

Conclusion

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

December 17, 2004